

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, *ex rel.*)
JAMES F. ALLEN,)
)
Relator – Plaintiff,)
v.)
)
ALERE HOME MONITORING, INC.;) Civil Action No. 1:16-CV-11372-PBS
ROCHE HEALTH SOLUTIONS, INC.;)
ADVANCED CARDIO SERVICES;)
CARDIOLINK CORP.; MDINR, LLC;)
PATIENT HOME MONITORING, INC.;)
TAMBRA INVESTMENTS, INC. d/b/a)
REAL TIME DIAGNOSTICS; and)
US HEALTHCARE SUPPLY, LLC,)
)
Defendants.)
)

**DEFENDANT PATIENT HOME MONITORING, INC.'S
MEMORANDUM OF LAW IN SUPPORT OF ITS
MOTION TO DISMISS THE FIRST AMENDED COMPLAINT**

PATIENT HOME MONITORING, INC.,

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TABLE OF CONTENTS

TABLE OF AUTHORITIES	ii
INTRODUCTION	1
FACTUAL BACKGROUND	3
ARGUMENT	6
I. The Court Should Apply the Applicable Pleading Standards and Dismiss Relator's Claims against PHM.....	6
II. The Court Should Dismiss with Prejudice Count I and Count II for Failing to Satisfy the Pleading Requirements under Fed. R. Civ. P. 12(b)(6) or 9(b).....	7
A. Relator Pleads No Facts Showing that PHM Presented or Caused to Be Presented Any False Claim, or Made or Used a False Record or Statement to Get a False Claim Paid. 8	
B. Relator Pleads No Facts Showing That PHM Provided Medically Unnecessary Services.....	10
C. Relator Pleads No Facts Showing That PHM Knowingly Made False Claims or Statements to the Government.....	13
III. The Court Should Dismiss with Prejudice Count III for "Reverse False Claim" because Relator Does Not Even Attempt to Allege Supporting Facts.....	14
IV. The Court Should Dismiss with Prejudice Counts IV and V for Lack of Standing.....	15
V. Relator's Claims Fail Due to the Public Disclosure Bar.....	15
CONCLUSION.....	18
CERTIFICATE OF SERVICE	19

TABLE OF AUTHORITIES**Cases**

<i>Ashcroft v. Iqbal</i> , 556 U.S. 662 (2009)	6
<i>Bell Atl. Corp. v. Twombly</i> , 550 U.S. 544 (2007)	6, 13
<i>D'Agostino v. EV3, Inc.</i> , 845 F.3d 1 (1st Cir. 2016).....	10
<i>In re Pharm. Industry Average Wholesale Price Litigation</i> , No. 01-12257-PBS, 2007 WL 4287572 (D. Mass. Dec. 6, 2007)	15
<i>North Am. Catholic Educ. Programming Found., Inc. v. Cardinale</i> , 567 F.3d 8 (1st Cir. 2009)	13
<i>Ocasio-Hernandez v. Fortuno-Burset</i> , 640 F.3d 1 (1st Cir. 2011)	6
<i>Ruiz v. Bally Total Fitness Holding Corp.</i> , 496 F.3d 1 (1st Cir. 2007)	3
<i>United States ex rel. Bartz v. Ortho-McNeil Pharm., Inc.</i> , 856 F. Supp.2d 253 (D. Mass. 2012)	6
<i>United States ex rel. Gagne v. City of Worcester</i> , 565 F.3d 40 (1st Cir. 2009)	6, 8
<i>United States ex rel. Ge v. Takeda Pharm. Co.</i> , 737 F.3d 116 (1st Cir. 2013)	7
<i>United States ex rel. Hagerty v. Cyberonics</i> , 844 F.3d 26 (1st Cir. 2016).....	10, 16
<i>United States ex rel. Hutcheson v. Blackstone Med., Inc.</i> , 647 F.3d 377 (1st Cir. 2011)	6, 13
<i>United States ex rel. Karvelas v. Melrose Wakefield Hosp.</i> , 360 F.3d 220 (1st Cir. 2004), <i>abrogated on other grounds by Allison Engine Co. v. United States ex rel. Sanders</i> , 553 U.S. 662 (2008).....	7

<i>United States ex rel. Loughren v. Unum Group,</i> 613 F.3d 300 (1st Cir. 2010)	7
<i>United States ex rel. Nowak v. Medtronic, Inc.,</i> 806 F. Supp.2d 310 (D. Mass. 2011)	7, 10
<i>United States ex rel. Ondis v. City of Woonsocket,</i> 587 F.3d 49 (1st Cir. 2009)	16
<i>United States ex rel. Osheroff v. Humana, Inc.,</i> 776 F.3d 805 (11th Cir. 2015).....	16
<i>United States ex rel. Purcell v. MWI Corp.,</i> 807 F.3d 281 (D.C. Cir. 2015), <i>cert. denied</i> , 137 S. Ct. 625 (2017).....	12
<i>United States ex rel. Repko v. Guthrie Clinic, P.C.,</i> 490 Fed. Appx. 502 (3rd Cir. 2012).....	16
<i>United States ex rel. Rost v. Pfizer,</i> 507 F.3d 720 (1st Cir. 2007)	8, 9
<i>United States ex rel. Walsh v. Eastman Kodak Co.,</i> 98 F. Supp.2d 141 (D. Mass. 2000)	15
<i>United States ex rel. Wilson v. Kellogg Brown & Root, Inc.,</i> 525 F.3d 370 (4th Cir. 2008).....	12
<i>United States ex rel. Winkelman v. CVS Caremark Corp,</i> 827 F.3d 201 (1st Cir. 2016)	16, 17, 18
<i>United States v. Heart Research Found.,</i> 996 F.2d 7 (1st Cir. 1993)	14

Statutes

31 U.S.C. § 3729(a)(1)(A)	3
31 U.S.C. § 3729(a)(1)(B)	3, 8
31 U.S.C. § 3729(a)(1)(G)	3, 14
31 U.S.C. § 3729(b)(2)	8
31 U.S.C. § 3729(b)(3)	14

31 U.S.C. § 3730(e)(4)(A)	15
31 U.S.C. § 3730(e)(4)(B)	18

Rules

Fed. R. Civ. P. 12(b)(6).....	2, 7, 10, 14
Fed. R. Civ. P. 9(b)	passim

Defendant Patient Home Monitoring, Inc. (“PHM”) submits this Memorandum of Law in support of its Motion to Dismiss the First Amended Complaint (“Amended Complaint”) filed by relator James F. Allen (“Relator”).

INTRODUCTION

Relator, who was never PHM’s patient, seeks to turn a debate about the medical necessity of self-administered blood tests prescribed for patients other than himself into a lucrative *qui tam* suit. This effort must fail because, among other reasons, Relator’s pleadings do not identify even a single allegedly false claim submitted by PHM to the government.

Indeed, the Amended Complaint provides *no facts* to support Relator’s conclusory allegations that PHM and the other defendants somehow coerced or misled patients or their doctors into conducting blood tests that were not medically necessary. Specifically, there is no basis for concluding, despite Realtor’s rhetorical urging, that: (1) any claims submitted by PHM for reimbursement were not medically necessary for the individual patients enrolled by their individual physicians in PHM’s program; (2) the decision to exclude non-weekly testers from PHM’s program was improper in any way, let alone led to a single false claim to the government; or (3) marketing materials that included certain medical journal references, but not Relator’s preferred references, were *false*, or *caused* a medically unnecessary prescription to be written.

In his lengthy Amended Complaint, which was filed after the government declined to intervene in this suit, Relator contends that PHM and other defendants violated the False Claims Act (“FCA”) because they decided to service only patients for whom a doctor prescribed weekly blood monitoring tests. PHM provides in-home patient testing and monitoring services for patients on long-term warfarin (anticoagulant) therapy. Its company protocols are designed to

service patients who require weekly testing, rather than patients who require less frequent testing. As Relator concedes, all patients enrolled with PHM (or the other defendants) require a doctor's prescription for the testing. The (undated) PHM prescription form attached to the Amended Complaint as Exhibit 5 (entitled "Self-Testing Referral Form/RX and Letter of Medical Necessity") makes clear that upon enrollment with PHM, a doctor certifies that it is medically necessary for his or her patient to be tested weekly, that the doctor is looking for the test results to fall within a doctor-designated range, and that the patient or the patient's caregiver should "report the results on a weekly basis to Patient Home Monitoring (PHM)" Am. Compl., Ex. 5.

In the face of this background, Relator contends that PHM and the other defendants *must have* submitted false claims for reimbursement because his own doctor believes that Relator only required monthly in-home testing, and Relator believes the standard of care for patients on warfarin therapy rarely requires weekly in-home patient testing. A lawsuit under the FCA, however, is not the proper forum in which to debate industry standards of care or individual medical judgments. No facts in the Amended Complaint support an allegation that PHM submitted a claim for reimbursement for a test that was not medically necessary.

Thus, the Court should dismiss Count I ("false claim theory") and Count II ("false statement theory") under the FCA as to PHM because Relator fails to meet the plausibility and particularity requirements of Fed. R. Civ. P. 12(b)(6) and 9(b). In short, the Amended Complaint fails to set forth non-conclusory factual allegations regarding the material elements of each count. Moreover, Relator also fails to offer sufficient allegations concerning the "who, what, when, where, and how" of the allegedly fraudulent conduct and purportedly false claims or statements to the government.

The Court should dismiss Count III (“reverse false claim theory”) under the FCA as to PHM because the Amended Complaint does not even attempt to offer allegations concerning this count and does nothing more than recite the statutory language.

The Court should dismiss Count IV (“payment under mistake of fact”) and Count V (“unjust enrichment”) because Relator lacks standing to assert these common law claims on behalf of the United States.

Finally, the Court should dismiss the Amended Complaint as to PHM because it is based on nothing more than publicly available information found on the Internet, and therefore, Relator’s claims fail due to the public disclosure bar.

For these reasons, as well as the reasons set forth below and in the Memoranda of Law submitted by the other co-defendants in this action, the Court should dismiss the claims against PHM with prejudice.

FACTUAL BACKGROUND¹

Relator filed this *qui tam* FCA action in 2016. After the Government declined to intervene, Relator filed and served the Amended Complaint. In the Amended Complaint, Relator asserts five claims against all defendants, including PHM. Count I asserts a false claim theory pursuant to the FCA, 31 U.S.C. § 3729(a)(1)(A); Count II is a false records or statements theory under the FCA, 31 U.S.C. § 3729(a)(1)(B); Count III is a reverse false claim theory under the FCA, 31 U.S.C. § 3729(a)(1)(G); Count IV asserts a common law claim of payment under mistake of fact; and Count V asserts a common law claim of unjust enrichment.

¹ Any well-pleaded, plausible facts alleged in the Amended Complaint are assumed to be true solely for the purpose of this Motion. *Ruiz v. Bally Total Fitness Holding Corp.*, 496 F.3d 1, 5 (1st Cir. 2007).

The lawsuit concerns in-home blood testing for patients on long-term warfarin therapy. Am. Compl. ¶ 2. Warfarin is an anti-clotting agent – normally a lifelong treatment – prescribed to patients with certain cardiac conditions. Am. Compl. ¶ 73. The tests (“PT/INR tests”) measure the prothrombin time (“PT”) using the international normalized ratio (“INR”), which can rise or fall during warfarin treatment. *Id.* ¶ 2. Due to the narrow PT/INR therapeutic range and potentially fatal risks of out-of-range PT/INR results, warfarin patients must regularly undergo blood testing so their physicians can adjust the warfarin dose if necessary. *Id.* ¶ 77.

While many warfarin patients, including Relator, are tested in a medical office or clinic, defendants in this lawsuit provide in-home self-testing services for warfarin patients. Am. Compl. ¶¶ 2, 35. The National Coverage Determination for home PT/INR testing promulgated by the Centers for Medicare & Medicaid Services (“CMS”) allow reimbursement for in-home PT/INR self-testing performed weekly. *Id.* ¶ 5. Physicians determine the patient’s appropriate testing frequency. *Id.* ¶ 10, 40. PHM, along with several other defendants, limits its testing services to patients who require weekly testing and declines to enroll patients seeking less frequent testing. *Id.* ¶ 4.

While the Amended Complaint contains various unspecific, unsubstantiated allegations against the in-home PT/INR self-testing industry generally², Relator’s allegations against PHM are sparse:

- PHM, along with several other defendants, requires its patients to test their PT/INR weekly. Am. Compl. ¶ 4.

² PHM summarizes here Relator’s factual allegations to the extent they relate specifically to PHM. As to allegations concerning warfarin testing and Medicare coverage generally, PHM refers to and incorporates by reference the summary of factual allegations and related arguments contained in the Memorandum of Law filed by co-defendant Roche Health Solutions, Inc., Dkt. 58, p. 4-6 (A. Warfarin and INR Testing; B. INR Testing Options; C. Medicare Coverage of Patient Self-Testing).

- PHM, along with several other defendants, allows physicians to elect to receive monthly summaries of the patient's weekly in-home, in-range testing results. Am. Compl. ¶¶ 207, 251.
- PHM, along with several other defendants, has distributed "marketing materials" (at an unnamed time or place) referencing a 2006 article titled "Self-monitoring of oral anticoagulation: a systematic review and meta-analysis" supporting frequent home monitoring as a superior method of PT/INR testing (the "2006 Heneghan Study"). Am. Compl. ¶ 130.
- PHM, along with the other defendants, targeted its business to the Medicare market and believed that physicians could realize additional revenues resulting from in-home PT/INR testing. Am. Compl. ¶¶ 203-206.
- In 2015, PHM submitted bills for PT/INR testing averaging 2.90 tests per patient per month (80,868 tests taken by 2,323 patients). Am. Compl. ¶ 266(d).
- Relator contacted PHM in December 2014 about enrolling in its PT/INR home-testing program and inquired about testing less than once per week. Am. Compl. ¶ 198. PHM's representative told him that PHM required weekly testing and that, if he wished to test less frequently, he could not enroll in PHM's program as a matter of internal policy. Am. Compl. ¶¶ 198, 202. PHM's representative also inaccurately told him that Medicare requires weekly testing. Am. Compl. ¶¶ 199-202.
- Relator did not enroll in PHM's home-testing program. Am. Compl. ¶ 202.

Nowhere in the Amended Complaint does Relator make specific factual allegations of a false claim or statement made or caused to be made by PHM to the government, or any specific medically unnecessary procedure performed by PHM, let alone that PHM had the requisite scienter. In fact, as the Relator was never a patient of PHM, he has no allegations about any specific patient, provider, services, or billings relating to PHM, whether perfectly legitimate or allegedly fraudulent. Simply put, Relator's knowledge about PHM amounts to a single email exchange with a PHM representative in December 2014 (which exchange led to no medical testing or billing whatsoever), and whatever he could find on the Internet or in other publicly available sources.

ARGUMENT

I. The Court Should Apply the Applicable Pleading Standards and Dismiss Relator's Claims against PHM.

To overcome a motion to dismiss, “[f]actual allegations must be enough to raise a right to relief above the speculative level.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 545 (2007). “[The] complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face. A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). These principles ensure that Rule 12 “does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions.” *Iqbal*, 556 U.S. at 678-79. “[B]asic deficienc[ies] [in a complaint] should . . . be exposed at the point of minimum expenditure of time and money by the parties and the court.” *Twombly*, 550 U.S. at 558.

In resolving this motion, the Court “should begin by identifying and disregarding statements in the complaint that merely offer ‘legal conclusions couched as fact’ or ‘threadbare recitals of the elements of a cause of action.’” *Ocasio-Hernandez v. Fortuno-Burset*, 640 F.3d 1, 12 (1st Cir. 2011) (quoting *Iqbal*, 556 U.S. at 678). “A suit will be dismissed if the complaint does not set forth factual allegations, either direct or inferential, respecting each material element necessary to sustain recovery under some actionable legal theory.” *United States ex rel. Bartz v. Ortho-McNeil Pharm., Inc.*, 856 F. Supp.2d 253, 259 (D. Mass. 2012) (dismissing FCA claims) (quoting *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 384 (1st Cir. 2011) (internal citations omitted)). Furthermore, claims brought under the various subsections of the FCA are also subject to the heightened pleading requirements for fraud set forth in Fed. R. Civ. P. 9(b). *United States ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 45 (1st Cir. 2009).

II. The Court Should Dismiss with Prejudice Count I and Count II for Failing to Satisfy the Pleading Requirements under Fed. R. Civ. P. 12(b)(6) or 9(b).

Count I and Count II of the First Amended Complaint should be dismissed with prejudice for failing to state a claim for relief that is plausible on its face. Congress enacted the FCA to prohibit “the submission of false or fraudulent claims to the Government.” *United States ex rel. Karvelas v. Melrose Wakefield Hosp.*, 360 F.3d 220, 224 (1st Cir. 2004), *abrogated on other grounds by Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662 (2008). The lynchpin of an FCA claim is a “claim for payment” that is presented to the government. *Id.* Relator must “state with particularity the circumstances constituting fraud or mistake,” including the “who, what, when, where, and how of the alleged fraud.” *United States ex rel. Ge v. Takeda Pharm. Co.*, 737 F.3d 116, 123 (1st Cir. 2013).

To assert the claim alleged in Count I (false claim theory), the Relator must allege facts showing that the defendant (1) “present[ed] or cause[d] to be presented to the United States government, a claim for approval or payment, where (2) that claim is false and fraudulent, and (3) the action was undertaken ‘knowingly,’ in other words, with actual knowledge of the falsity of the information contained in the claim, or in deliberate ignorance or reckless disregard of the truth or falsity of that information.” *Karvelas*, 360 F.3d at 225; *United States ex rel. Nowak v. Medtronic, Inc.*, 806 F. Supp.2d 310, 342 n. 19 (D. Mass. 2011) (applying same standard before and after 2009 amendments to FCA). *See also United States ex rel. Loughren v. Unum Group*, 613 F.3d 300, 307 (1st Cir. 2010) (the false or fraudulent claim must be material).

To assert the claim alleged in Count II (false statement theory), the Relator must allege facts showing that the defendant made or used “a false record or statement material to a false or fraudulent claim,” which is a “request or demand” for payment “that is presented to [the government] or is made to a contractor, grantee, or other recipient” for use of federal funds.” 31

U.S.C. §§ 3729(a)(1)(B) and (b)(2). “[R]elator must still connect the allegedly fraudulent statement to a planned claim on the government fisc, must show that the defendant intended the statement would have a material effect on the government’s decision to pay a claim, and must plead the facts of the fraud with sufficient particularity to satisfy Rule 9(b).” *Gagne*, 565 F.3d at 46 n. 7.

As described further below, Counts I and II fail because (a) Relator pleads no facts showing that PHM presented or caused others to present a false claim, or made or used a false record or statement to get a false claim paid; (b) Relator pleads no facts to establish that any medically unnecessary tests were performed; and (c) Relator pleads no facts showing that PHM had actual knowledge of, or deliberately ignored or recklessly disregarded, the falsity of any claim. Relator cannot satisfy these pleading requirements, and his FCA claims fail as a matter of law and should be dismissed with prejudice.

A. Relator Pleads No Facts Showing that PHM Presented or Caused to Be Presented Any False Claim, or Made or Used a False Record or Statement to Get a False Claim Paid.

To succeed on his claims, Relator must “sufficiently establish that false claims were submitted for government payment in a way that satisfies the particularity requirement [of Rule 9(b).]” *United States ex rel. Rost v. Pfizer*, 507 F.3d 720, 733 (1st Cir. 2007). Relator makes no effort, however, to plead the “who, what, when, where, and how” of PHM’s supposed fraud. Relator does not allege who specifically at PHM knowingly participated in the fraud, or when the scheme was hatched, how or where such decisions were made, or if anything else was done in furtherance of the alleged fraud.

While Relator’s allegations against PHM are virtually non-existent, what Relator *does not* allege is even more telling. Relator nowhere alleges specific facts supporting any claim that

PHM submitted or caused to be submitted a false claim for reimbursement to Medicare or any government agency. Relator nowhere alleges specific facts showing that PHM performed services without a prescription or certification from a patient's physician affirming that the prescribed services were medically necessary. Relator nowhere alleges specific facts showing that PHM billed Medicare or any government agency for services that it did not perform. Relator nowhere alleges specific facts as to how any effort by PHM to target its business to enrollees insured by Medicare amounts to a false claim or statement under the FCA. Relator nowhere alleges specific facts showing that PHM made or used specific false statements in order to get a specific claim paid. Relator does not assert any of these allegations against PHM because he has no knowledge or basis for doing so.

Furthermore, Relator nowhere alleges how PHM's decision to limit its services to patients who received prescriptions for weekly testing amounts to a false claim, and points to no legal requirement anywhere forcing PHM to provide services to patients requiring a different level of testing. PHM, like the other co-defendants, has no legal obligation to provide testing services to patients for any and all testing frequencies and is entitled to limit its services to patients who require weekly testing pursuant to a prescription or physician authorization affirming medical necessity.³ As PHM cannot be compelled to provide services to patients who are not prescribed weekly testing, PHM's weekly testing requirement cannot form the basis of an FCA claim.

The Court should reject Relator's baseless claims and dismiss the First Amended Complaint with prejudice. Relator relies on conclusory allegations and generalizations not tied to any particular false claim, which does not satisfy the requirements of Rule 9(b). *See Rost, 507*

³ PHM incorporates by reference the arguments in this regard set forth in the Memorandum of Law of co-defendant Roche Health Solutions, Inc., Dkt. 58 (Section III.A.2, pp. 13-16).

F.3d at 733. The First Amended Complaint lacks the necessary allegations to raise any inference of fraud, and should therefore be dismissed under Rule 12(b)(6) and 9(b).

B. Relator Pleads No Facts Showing That PHM Provided Medically Unnecessary Services.

Having failed to provide any specific allegations showing that a false statement was submitted to the government by PHM for any particular patient or test, Relator argues that defendants, including PHM, *must have* performed medically unnecessary testing services because weekly testing does not satisfy the standard of care as Relator understands it. This approach fails to state a FCA claim, too.

To state an FCA claim based on medical necessity, Relator must satisfy a higher pleading standard and provide specific factual evidence establishing that the PT/INR testing services provided were medically unnecessary. *See United States ex rel. Nowak v. Medtronic, Inc.*, 806 F. Supp.2d 310, 354 (D. Mass. 2011) (dismissing FCA claims based on statistics because, “in the medical device context,” each “individual health care provider’s medical judgment is an essential element of [relator’s] FCA claim, without which she cannot demonstrate that a *false or fraudulent* claim was submitted”); *United States ex rel. Hagerty v. Cyberonics*, 844 F.3d 26 (1st Cir. 2016) (affirming dismissal of FCA claim for allegedly promoting medically unnecessary device replacements for failure to allege fraud with required particularity); *D’Agostino v. EV3, Inc.*, 845 F.3d 1 (1st Cir. 2016) (same).

The Amended Complaint wholly fails to satisfy this requirement. First, Relator does not allege any patient-specific facts – any specific test performed on any specific patient on any specific date as prescribed by any specific physician – establishing that PHM provided testing services that were medically unnecessary. To the contrary, Relator’s allegations show that PHM would not enroll him and did not perform any medically unnecessary testing on him where

Relator was not instructed by his doctor to test on a weekly basis. Am. Compl. ¶¶ 198, 202.

Indeed, Relator provides email communications from PHM's representatives stating "in order to come on board with our company, we require all of our patients to test weekly" and "[i]f you would only like to test once a month unfortunately we do not allow that due to our company policy and protocol, and our services may not be the best option for you."⁴

Second, Relator points to no authority supporting any claim that differing medical opinions on the appropriate frequency of self-testing for individual patients amounts to a false claim under the FCA, especially without any plausible allegation that PHM performed services not prescribed by a physician as medically necessary.⁵

Third, Relator fails to provide any basis to infer that a physician's election to receive monthly summaries of weekly in-range testing results means that the weekly tests were medically unnecessary, were not reported to the doctor, or that any specific false claim resulted.

⁴ Relator alleges that the PHM representative inaccurately told him that Medicare requires weekly testing. Am. Compl. ¶¶ 199-200. While it is not clear that her initial message said that, even if it did, the PHM representative corrected the statement in her subsequent email, stating that weekly testing was required by PHM's own "policies and protocols." *Id.* ¶ 202. Relator cannot claim that this single statement to him personally caused a false claim by him, where he was never enrolled with or tested by PHM, nor can he plausibly allege that this single statement to him caused anyone else to submit a false claim.

⁵ As set forth in detail in the Memorandum of Law of co-defendant Roche Health Solutions, Inc., differences of medical opinion cannot establish falsity under the FCA. Dkt. 58, Section III.A.3(i), pp. 17-20. Moreover, Relator's characterization of the medical documentation he cites does not necessarily support his "opinion" of the standard of care for home-testing patients. *Id.* at 18. This record reveals, at a minimum, a range of opinions regarding the recommended frequency of testing required for home-testing patients, further undermining Relator's ability to demonstrate any falsity in PHM's alleged reference to the 2006 Heneghan Study, let alone any "false" prescription "caused" by such unidentified, untethered marketing efforts. There is no dispute that prescription decisions should be made on an individual basis given that CMS describes warfarin as a "'black-box' drug whose dosage must be closely monitored to avoid serious complications." Am. Compl. ¶ 75; National Coverage Determination for home PT/INR testing promulgated by CMS (cited in Am. Compl. ¶ 75).

Am. Compl. ¶¶ 207, 251. Relator alleges no specific facts that would permit a conclusion that PHM failed to comply with the obligation to report test results to physicians as described in CMS Manual Chapter 32, Section 60.4.2 (cited in Am. Compl. ¶ 249). The goal of warfarin treatment is to maintain patients' INR within a therapeutic range determined by the patient's physician, and due to the potentially fatal risks of out-of-range PT/INR results, warfarin patients must regularly undergo blood testing so their physicians can adjust, if necessary, the dose. *Id.* ¶¶ 74, 77. Receipt of a monthly report showing in-range tests confirms that the patient's results did not measure out-of-range during the prior month, especially where the physician has specifically identified the target range for the particular patient. Am. Compl., Ex. 5 (PHM form calls for doctor to identify a "Target INR Range: __ (low) to __ (high)"). In all events, there is no basis for concluding that any specific test results were not reported for any specific patient resulting in a "false claim," let alone a knowingly false claim. *See United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 287-88 (D.C. Cir. 2015), *cert. denied*, 137 S. Ct. 625 (2017) ("To be liable under the FCA, a defendant must have made the false claims knowingly," and that, accordingly, "the FCA does not reach an innocent, good-faith mistake about the meaning of an applicable rule or regulation," nor "claims made based on reasonable but erroneous interpretations of a defendant's legal obligations"); *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 376-378 (4th Cir. 2008) (affirming district court's dismissal of FCA claim, stating "An FCA relator cannot base a fraud claim on nothing more than his own interpretation" of a legal obligation). *See also* infra Section II.C.

Under even the most charitable reading of the Amended Complaint, Relator's empty claims of medically unnecessary testing do not "raise a right to relief above the speculative

level,” *Twombly*, 550 U.S. at 555, let alone plead fraud with particularity, and should be dismissed.

C. Relator Pleads No Facts Showing That PHM Knowingly Made False Claims or Statements to the Government.

The Amended Complaint offers no support for any claim that PHM *knowingly* made false claims or statements to the government. “[L]iability cannot arise under the FCA unless a defendant acted knowingly.” *Blackstone Med.*, 647 F.3d at 388. At a minimum, to be liable under the FCA for an allegedly false claim or statement to the government, the statement must have been knowingly false when made. *Id.* at 390. “[C]ourts have uniformly held inadequate a complaint’s general averment of defendant’s ‘knowledge’ of material falsity, unless the complaint also sets forth specific facts that make it reasonable to believe that defendant knew that a statement was materially false or misleading.” *North Am. Catholic Educ. Programming Found., Inc. v. Cardinale*, 567 F.3d 8, 13 (1st Cir. 2009).

Relator nowhere meets this standard – indeed, Relator fails to allege how any claims or statements by PHM to the government were false *at all*, and fails to plausibly suggest how PHM’s weekly testing requirement leads to an inference that it knew that medically unnecessary procedures were being ordered by any doctor – let alone numerous doctors. In fact, Relator is forced to acknowledge that PHM requires a signature from a healthcare provider as to Medical Necessity/Prescription. The cited PHM form provides: “Patient self-testing is a service that requires the patient or the patient’s caregiver to administer a PT/INR test and report the results on a weekly basis to [PHM] for the duration of the patient’s anticoagulation therapy.” Am. Compl. ¶ 207, Ex. 5. In the absence of supporting allegations, Relator fails to meet the scienter requirement for his claims.

III. The Court Should Dismiss with Prejudice Count III for “Reverse False Claim” because Relator Does Not Even Attempt to Allege Supporting Facts.

Relator fails to make even an attempt to satisfy Fed. R. Civ. P. 12(b)(6) or 9(b) under Count III for “reverse false claim” in violation of 31 U.S.C. § 3729(a)(1)(G). To assert a “reverse false claim,” Relator must plead facts showing that the defendant “knowingly ma[de], use[d] or cause[d] to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceal[ed] or knowingly and improperly avoid[ed] or decrease[d] an obligation to pay or transmit money or property to the Government.” 31 U.S.C. § 3729(a)(1)(G). The statute defines obligation to mean “an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute of regulation, or from the retention of any overpayment.” 31 U.S.C. § 3729(b)(3).

Besides reciting the statutory language in the paragraphs under the Count III heading (¶¶279-281), Relator offers no facts suggesting that PHM had an obligation to pay or transmit money or property to the federal government that was concealed, avoided, or decreased by any of the alleged conduct in the Amended Complaint. To the contrary, Relator’s theory of the case is premised on the exact opposite – alleged improper claims *for* payment from the government. *See, e.g., United States v. Heart Research Found.*, 996 F.2d 7 (1st Cir. 1993) (finding that a reverse false claim is not actionable under the FCA subsections relating to false claims or false statements). Given the utter lack of even an attempt to support the claim with factual allegations, and in addition to the reasons stated with respect to Count I and Count II above, the Court should dismiss Count III.

IV. The Court Should Dismiss with Prejudice Counts IV and V for Lack of Standing.

In addition to failing to allege any false claim submitted or caused to be submitted by PHM to the government, Relator also does not state a claim under Count IV (“payment under mistake of fact”) and Count V (“unjust enrichment”) because he lacks standing to assert common law claims on behalf of the United States. “[T]he FCA does not give relators the right to assert common law claims on behalf of the United States.” *See United States ex rel. Walsh v. Eastman Kodak Co.*, 98 F. Supp.2d 141, 149 (D. Mass. 2000) (dismissing Relator’s common law claims of payment under mistake of fact and unjust enrichment with prejudice for lack of standing); *In re Pharm. Industry Average Wholesale Price Litigation*, No. 01-12257-PBS, 2007 WL 4287572, *5 (D. Mass. Dec. 6, 2007) (Saris, J.) (dismissing with prejudice common law claims of fraud and unjust enrichment asserted on behalf of the government for lack of standing). As Relator lacks standing, under the FCA or otherwise, to assert common law claims on behalf of the United States, and does not and cannot claim that *he* was defrauded or unjustly enriched by PHM, the Court should dismiss these claims.

V. Relator’s Claims Fail Due to the Public Disclosure Bar.

The Court should dismiss Relator’s FCA claims because they are barred by the public disclosure doctrine and he does not qualify for the original source exception. The FCA states, in pertinent part, “The court shall dismiss an action or claim under this section [...] if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed – (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party; (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or (iii) from the news media, unless [...] the person bringing the action is an original source of the information.” 31 U.S.C. § 3730(e)(4)(A). “In evaluating

substantial similarity, an inquiring court should bear in mind the core purpose of the FCA: to encourage suits by individuals with valuable knowledge of fraud unknown to the government.”

United States ex rel. Winkelman v. CVS Caremark Corp, 827 F.3d 201, 210 (1st Cir. 2016)

(citing *United States ex rel. Ondis v. City of Woonsocket*, 587 F.3d 49, 58 (1st Cir. 2009))

(affirming district court’s dismissal of FCA claim based on public disclosure bar). “The public disclosure bar safeguards this interest because when the material elements of a fraud are already in the public domain, the government has no need for a relator to bring the matter to its attention. It follows logically, we think, that a complaint that targets a scheme previously revealed through public disclosures is barred even if it offers greater detail about the underlying conduct.” *Id.* (internal citations omitted).

First, Relator’s claims are barred because they are the same allegations or transactions publicly disclosed in the news media, namely PHM’s own website. For the purposes of the public disclosure bar, “news media” includes information readily available on the Internet. *See, e.g., United States ex rel. Osheroff v. Humana, Inc.*, 776 F.3d 805, 808 (11th Cir. 2015) (affirming district court’s dismissal of FCA claim under public disclosure bar based on information found on clinics’ websites); *United States ex rel. Repko v. Guthrie Clinic, P.C.*, 490 Fed. Appx. 502 (3rd Cir. 2012) (affirming district court’s dismissal of FCA claim under public disclosure bar based on information found on websites); *United States ex rel. Hagerty v. Cyberonics*, 95 F. Supp. 3d 240, 257 n.7 (D.Mass. 2015), *aff’d*, 844 F.3d at 26 (noting that “courts that have considered the issue have construed the term to include readily accessible websites”).

All of the purported “facts” on which Relator bases his claims against PHM can be derived from a cursory review of PHM’s website (www.myphm.com). In short, the website discloses, among other things, that:

- PHM requires patients to self-test weekly;
- PHM allows doctors to select the type of reporting that they prefer;
- PHM identifies revenue opportunities for doctors whose patients participate in PHM’s home testing, via identified Medicare billing codes;
- PHM cites clinical research supporting the benefits weekly in-home testing as compared to monthly in-clinic testing; and
- PHM cites logistical benefits for doctors whose patients participate in PHM’s home testing program.

In light of this background, there can be no dispute that the entire claim against PHM stems from publicly available materials, and therefore, Relator’s claim is barred. Relator does not even provide specific examples of the fraud he alleges, but instead weaves together a story based upon “must have been” conjecture and a stretched interpretation of carefully selected and excerpted medical sources in order to promote an argument that weekly home-tests must not be medically necessary for individual patients, despite the opinions, prescriptions, and directions of their treating physicians. All of the essential elements of the purportedly fraudulent scheme outlined in the Amended Complaint are freely available and readily accessible on the Internet, and Relator adds nothing “sufficiently significant” or “essential.” *Winkelman*, 827 F.3d at 208. His FCA claims are thus barred as publicly disclosed under the FCA.

Second, Relator cannot claim to be covered by the FCA’s original source exception. A relator is considered an original source if the relator “either (1) prior to a public disclosure [...]”

has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) [...] has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and [...] has voluntarily provided the information to the Government before filing an action under this section.” 31 U.S.C. § 3730(e)(4)(B); *see Winkelman*, 827 F.3d at 211. As stated above, Relator’s claim against PHM is based on publicly-available documents found on PHM’s website, and a single email exchange with a PHM employee who told Relator what was already publicly available on PHM’s website, namely that PHM only services patients who have a prescription for weekly testing. Accordingly, Relator’s FCA claims should also be dismissed on the basis of the public disclosure bar.

CONCLUSION

WHEREFORE, for the reasons stated above along with the arguments advanced by the other co-defendants in this action, defendant Patient Home Monitoring, Inc. respectfully requests that the Court dismiss the First Amended Complaint as to Patient Home Monitoring, Inc., with prejudice.

Respectfully submitted,

PATIENT HOME MONITORING, INC.,

By its attorneys,

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Dated: February 16, 2018

CERTIFICATE OF SERVICE

I certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on the date specified below.

Dated: February 16, 2018

/s/ Sara Jane Shanahan

Sara Jane Shanahan